

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of)	
)	
Michael Hoey et. al.)	Group Art Unit: 3736
)	
App. Ser. No. 10/812,038)	
)	Examiner: Charles Alan Marmor II
Filed: March 29, 2004)	
)	
For: TISSUE DISCRIMINATION)	
AND APPLICATIONS IN)	
MEDICAL PROCEDURES)	
)	

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Signature: _____

Jonathan Spangler

RESPONSIVE AMENDMENT

Mail Stop Petition
Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

Dear Sir:

In response to the office action mailed September 21, 2004, having a shortened statutory period for response which expired December 21, 2004, please amend the above-identified application as follows.

IN THE SPECIFICATION:

Please replace the section entitled "CROSS-REFERENCES TO RELATED APPLICATIONS" with the following replacement section:

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a divisional of commonly owned and co-pending U.S. Patent Application Serial No. 09/860,648 filed May 18, 2001 and issued as U.S. Patent No. 6,760,616 on July 6, 2004, the complete disclosure of which is hereby incorporated herein by reference in its entirety for all purposes. Additionally, the present application claims benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application Serial No. 60/205,634 filed May 18, 2000; and U.S. Provisional Application Serial No. ~~60/243/465~~ 60/243,465 filed October 25, 2000; the entire contents of which are hereby expressly incorporated by reference into this disclosure as if set forth fully herein.

IN THE CLAIMS:

1. (Currently Amended) A method of ~~determining whether a conductive element of a probe is located adjacent to~~ identifying a characterized body tissue located adjacent to a conductive element of a probe comprising the steps of:
 - a) applying an electrical signal to the conductive element;
 - b) determining characteristics of the applied signal, including a phase angle; and
 - c) ~~determining whether the conductive element of a probe is located adjacent to~~ identifying a characterized body tissue located adjacent to the conductive element of a probe based on the phase angle of the applied signal, wherein said characterized body tissue comprises at least one of cortical bone[[,]] and cancellous bone, or cortical bone near the boundary with soft tissue.
2. (Currently Amended) The method of claim 1, wherein the determined characteristics of the applied signal include an impedance of the signal through the tissue.
3. (Previously Presented) The method of claim 1, wherein the probe comprises one of a cannula and a cathode.
4. (Previously Presented) The method of claim 1, wherein step a) applies signals having a range of predetermined frequencies to the conductive element.

5. (Currently Amended) The method of claim 1, wherein step c) includes ~~determining whether the conductive element of a probe is located adjacent to said tissue~~ identifying the characterized body tissue located adjacent to the conductive element of said probe based on the determined characteristics and frequency of the resulting signal.
6. (Previously Presented) The method of claim 1, wherein the conductive element is an electrode.
7. (Previously Presented) The method of claim 1, wherein the conductive element includes a pair of electrodes and the signal is passed between said electrodes.
8. (Previously Presented) The method of claim 1, wherein the signal is an electrical signal having a sliding frequency.
9. (Currently Amended) An article of manufacture for use in ~~determining whether a conductive element of a probe is located adjacent to~~ identifying a characterized body tissue located adjacent to a conductive element of a probe, the article of manufacture comprising computer readable storage media including program logic embedded therein that causes control circuitry to perform the steps of:
 - a) applying a signal to the conductive element;
 - b) determining characteristics of the applied signal, including a phase angle;and

- c) ~~determining whether the conductive element of a probe is located adjacent~~
~~to~~ identifying a characterized body tissue located adjacent to the
conductive element of a probe based on the phase angle of the applied
signal, wherein said characterized body tissue comprises at least one of
cortical bone~~[[,]]~~ and cancellous bone, ~~or cortical bone near the boundary~~
~~with soft tissue.~~
10. (Currently Amended) The article of manufacture of claim 9, wherein the
determined characteristics of the applied signal further include an impedance of
the signal through the tissue.
11. (Previously Presented) The article of manufacture of claim 9, wherein the probe
comprises one of a cannula and a cathode.
12. (Previously Presented) The article of manufacture of claim 9, wherein step a)
applies signals having a range of predetermined frequencies to the conductive
element.
13. (Currently Amended) The article of manufacture of claim 9, wherein step c)
includes ~~determining whether the conductive element of a probe is located~~
~~adjacent to said tissue~~ identifying the characterized body tissue located adjacent to
the conductive element of said probe based on the determined characteristics and
frequency of the resulting signal.

14. (Previously Presented) The article of manufacture of claim 9, wherein the conductive element is an electrode.
15. (Previously Presented) The article of manufacture of claim 9, wherein the conductive element includes a pair of electrodes and the signal is passed between said electrodes.
16. (Previously Presented) The article of manufacture of claim 9, wherein the signal is an electrical signal having a sliding frequency.
17. (Currently Amended) An apparatus for use in ~~determining whether a conductive element of a probe is located adjacent to~~ identifying a characterized body tissue located adjacent to a conductive element of a probe, the apparatus including:
 - a) means for applying a signal to the conductive element;
 - b) means for determining characteristics of the applied signal, including a phase angle of the signal; and
 - c) means for ~~determining whether the conductive element of a probe is located adjacent to~~ identifying a characterized body tissue located adjacent to the conductive element of a probe based on the phase angle of the applied signal, wherein said characterized body tissue comprises at least one of cortical bone~~[[,]]~~ and cancellous bone, ~~or cortical bone near the boundary with soft tissue.~~

18. (Currently Amended) The apparatus of claim 17, wherein the determined characteristics of the applied signal include an impedance of the signal through the tissue.
19. (Previously Presented) The apparatus of claim 17, wherein the probe comprises one of a cannula and a cathode.
20. (Previously Presented) The apparatus of claim 17, wherein means for applying a signal includes means for applying signals having a range of predetermined frequencies to the conductive element.
21. (Currently Amended) The apparatus of claim 17, wherein the means for ~~determining whether the conductive element of a probe is located adjacent to said tissue~~ identifying said tissue located adjacent to the conductive element of said probe includes means for determining whether the conductive element of a probe is located adjacent to said tissue based on the determined characteristics and frequency of the signal.
22. (Previously Presented) The apparatus of claim 17, wherein the conductive element is an electrode.

23. (Previously Presented) The apparatus of claim 17, wherein the conductive element includes a pair of electrodes and the signal is passed between said electrodes.
24. (Previously Presented) The apparatus of claim 17, wherein the signal is an electrical signal having a sliding frequency.

REMARKS

Claims 1-24 are currently pending in this application. In the Office Action mailed September 21, 2004 (the "Office Action"), claims 1-24 were rejected and claims 1, 2, 9, 10, 17 and 18 were objected to for various informalities. In response, claims 1-2, 5, 9-10, 13, 17-18 and 21 have been amended herewith. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and specification, and the following remarks.

I. Oath/Declaration

In paragraph 1 of the Office Action, the declaration was deemed to be defective because it did not identify the city and either state or foreign country of residence of each inventor. The Office Action correctly states that a copy of the Declaration for Utility or Design Application Using an Application Data Sheet (37 CFR 1.76) that was originally submitted with parent application U.S. Serial No. 09/860,648 was filed with the present application on March 29, 2004, and further states that no copy of an Application Data Sheet is in the file. The parent file did include a sheet containing "Inventor Information" including each inventor's name, postal address, and citizenship, as well as "Correspondence Information," "Application Information," and "Continuity Information." This sheet was inadvertently omitted with the copy of the declaration originally submitted in the present application. Applicants have resubmitted the copy of the original declaration as submitted with the parent application along with the copy of

the inventor information sheet that was also submitted with the original application, and further believe that this action should rectify the defect in the declaration.

II. Specification

In paragraph 2 of the Office Action, the disclosure was objected to for several informalities. Applicants have revised the section entitled "CROSS-REFERENCES TO RELATED APPLICATIONS" in order to correct these informalities. In particular, Applicants have added "and issued as U.S. Patent No. 6,760,616 on July 6, 2004" after "May 18, 2001" in order to correctly reflect the current status of the parent application. Furthermore, Applicants have replaced "60/243/465" with "60/243,465" in accordance with the Office Action. The remainder of the specification has been reviewed and no other errors are believed to exist. No new matter has been added.

III. Claim Objections

In paragraphs 4-9 of the Office Action, claims 1, 2, 9, 10, 17 and 18, respectively, were objected to because of several informalities. Claims 1, 2, 9, 10, 17 and 18 have been amended to correct these informalities, and applicants respectfully assert that these claim objections should be withdrawn as moot.

IV. Claim Rejections – 35 USC § 102

Claims 1-24 were rejected by the Office Action under 35 USC § 102(b) as being anticipated by U.S. Pat. No. 5,759,159 to Masreliez ("Masreliez"). Applicant respectfully traverses this rejection as set forth below.

In order for a reference to anticipate the present claimed invention under 35 USC 102(b), it must be shown that each and every element of the claim can be found in the reference. If it can be shown that one element of the claim is missing or not met by the cited reference, the rejection must be withdrawn as inappropriate.

Claim 1, as amended, recites a method of *identifying a characterized body tissue located adjacent to a conductive element of a probe* comprising the steps of (a) applying an electrical signal to the conductive element; (b) determining characteristics of the applied signal, including a phase angle; and (c) identifying a characterized body tissue located adjacent to the conductive element of a probe based on the phase angle of the applied signal, wherein said characterized body tissue comprises at least one of cortical bone and cancellous bone.

Claim 9, as amended, recites an article of manufacture for use in *identifying a characterized body tissue located adjacent to a conductive element of a probe*, the article of manufacture comprising computer readable storage media including program logic embedded therein that causes control circuitry to perform the steps of (a) applying an electrical signal to the conductive element; (b) determining characteristics of the applied signal, including a phase angle; and (c) identifying a characterized body tissue located adjacent to the conductive element of a probe based on the phase angle of the applied signal, wherein said characterized body tissue comprises at least one of cortical bone and cancellous bone.

Claim 17, as amended, recites an apparatus for use in *identifying a characterized body tissue located adjacent to a conductive element of a probe*, the apparatus including (a) means for applying a signal to the conductive element; (b) means for determining characteristics of the signal, including a phase angle of the signal; and (c) means for identifying a characterized body tissue located adjacent to the conductive element of a probe based on the phase angle of the applied signal, wherein said characterized body tissue comprises at least one of cortical bone and cancellous bone.

The Masreliez reference appears to be silent with regard to at least one element found in amended Claims 1, 9 and 17 of the claimed invention. Among other voids, the Masreliez reference does not disclose the element of Claims 1, 9 and 17 involving *identifying a characterized body tissue located adjacent to a conductive element of a probe*. The Masreliez reference appears to be concerned only with finding the apex of a root canal, particularly where the root canal ends and the patient's tissue begins (*col. 1, lines 23-25*). Notably, the apparatus and method in the Masreliez reference is focused on detecting changes in the node voltage $V_p(f_i)$ produced by the probe current $I_p(f_i)$, including phase angles \emptyset_1 - \emptyset_5 and amplitudes A_1 - A_5 which signal that the distal end of the probe is approaching body tissue (*col. 3 line 57 – col. 4, line 10*). The Masreliez reference neither teaches nor suggests identifying the type of body tissue that the probe may encounter. Rather, the Masreliez reference relies on the difference in impedance Z between the root canal (i.e. enamel) and body tissue (*col. 3, line 66 – col. 4, line 5, and*

col. 5, lines 20-25) to determine the location of the probe relative to body tissue in general.

Because the Masreliez reference is silent to at least one element of amended Claims 1, 9 and 17, it is respectfully requested that the rejection of Claims 1-24 in the Office Action be withdrawn. Claims 1, 9 and 17 are believed to be in proper condition for allowance and an indication of such is hereby earnestly solicited. Claims 2-8, 10-16, and 18-24, being dependent upon and further limiting independent Claims 1, 9 and 17, should be deemed allowable for the reasons set forth in support of the allowability of Claims 1, 9 and 17, as well as the additional features they contain.

V. Double Patenting

Claims 1-24 were rejected by the Office Action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,760,616. In response to this rejection, Applicants are willing to timely file a terminal disclaimer in compliance with 37 CFR 1.321(c) upon condition of allowance.

CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable reconsideration and allowance of the claims in this application is respectfully requested. In the event that there are any fees or charges associated with this submission, the Applicant hereby requests that any such fees or charges be made to Deposit Account No.: 50-2040 for Customer No.: 30,328.

In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
NUVASIVE, INC.

By: _____

Jonathan Spangler, Esq.
Registration No. 40,182

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Date: August 3, 2005

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Attorney Docket No.: 18608004910
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NO. 949 P. 3

PTO/SBA/TA (10-00)

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

As the below named inventor(s), I/we declare that:

This declaration is directed to:

- ☐ The attached application, or
☒ Application No. 09/860,648, filed on May 18, 2001,
☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including material information which became available between the filing date of the prior application and the National or PCT International filing date of the continuation-in-part application, if applicable; and

All statements made herein of my/our knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

THIS COPY OF THIS
DECLARATION IS
INTENDED FOR
SUBMISSION WITH THE
APPLICATION ATTACHED
HEREWITH,
(ATT REF No. 059US2)

FULL NAME OF INVENTOR(S)

Inventor one MICHAEL HOEY Date: 6/25/01
Signature: [Signature] Citizen of: US

Inventor two CORBETT W. STONE Date: 18 June 2001
Signature: [Signature] Citizen of: US

Inventor three KEVIN EOLEY Date: 7/1/01
Signature: [Signature] Citizen of: US

Inventor four _____ Date: _____
Signature: _____ Citizen of: _____

☐ Additional inventions are being named on _____ additional form(s) attached hereto.

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Correspondence Customer Number::

20350

Application Information

Title Line One::
Title Line Two::
Total Drawing Sheets::
Formal Drawings?::
Application Type::
Docket Number::
Secrecy Order in Patent Appl.?::

TISSUE DISCRIMINATION AND
APPLICATIONS IN MEDICAL PROCEDURES
3
Yes
Utility
18608004910
No

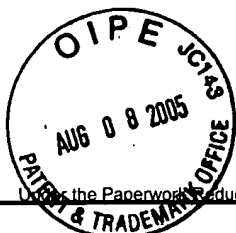
Continuity Information

This application is a::
> Application One::
Filing Date::
Patent Number::

NonProvisional
60/205,634
May 18, 2000

which is a::
>>Application Two::
Filing Date::
Patent Number::

60/243,465
October 25, 2000



PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031
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**TRANSMITTAL
FORM**

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Total Number of Pages in This Submission

Application Number	10/812,038
Filing Date	March 29, 2005
First Named Inventor	Michael F. Hoey
Art Unit	3736
Examiner Name	Charles A. Marmor, II
Attorney Docket Number	059US2

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input checked="" type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1. Copy of Date-stamped Return Postcard 2. Petition to Withdraw Holding of Abandonment 3. Petition to Revive for Unintentional Delay 4. Postcard
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	NuVasive, Inc.		
Signature			
Printed name	Jonathan Spangler		
Date	August 3, 2005	Reg. No.	40,182

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